30,000) – (number of companion animal veterinarians).

6. *Contiguous Area Considerations.*

Veterinary professional(s) in areas contiguous to an area being considered for designation will be considered excessively distant from the population of the area or overutilized if one of the following conditions prevails in each contiguous area:

(a) Veterinary professional(s) in the contiguous area are more than 60 minutes travel time from the center of the area being considered for designation (measured in accordance with paragraph C.1.(b) of this part).

(b) In the case of food animal veterinary professional(s), the VLU-to-food animal veterinarian ratio in the contiguous area is in excess of 5,000:1.

(c) In the case of companion animal veterinary professional(s), the population-to-companion animal veterinarian ratio in the contiguous area is in excess of 15,000:1.

C. *Determination of Degree-of-Shortage.*

Designated areas will be assigned to degree-of-shortage groups as follows:

Group 1—Areas with a food animal veterinarian shortage and no veterinarians.

Group 2—Areas (not included above) with a food animal veterinarian shortage and no food animal veterinarians.

Group 3—All other food animal veterinarian shortage areas.

Group 4—All companion animal shortage areas (not included above) having no veterinarians.

Group 5—All other companion animal shortage areas.

PART 5a—RURAL PHYSICIAN TRAINING GRANT PROGRAM

Sec.

AUTHORITY: Sec. 749B of the Public Health Service Act (42 U.S.C. 293k) as amended.

SOURCE: 75 FR 29451, May 26, 2010, unless otherwise noted.

§ 5a.1 Statutory basis and purpose.

This part implements section 749B(f) of the Public Health Service Act. These provisions define ''underserved rural community'' for purposes of the Rural Physician Training Grant Program.

§ 5a.2 Applicability.

This part applies to grants made under section 749B of the Public Health Service Act.

§ 5a.3 Definition of Underserved Rural Community.

Underserved Rural Community means a community:

(a) Located in:

(1) A non-Metropolitan County or Micropolitan county; or

(2) If it is within a Metropolitan county, all Census Tracts that are assigned a Rural-Urban Commuting Area (RUCAs) codes of 4–10; or

(3) Census Tracts within a Metropolitan Area with RUCA codes 2 and 3 that are larger than 400 square miles and have population density of less than 30 people per square mile; and

(b) Located in a current:

(1) Federally-designated Primary Health Care Geographic Health Professions Shortage Area, (under section 332(a)(1)(A) of the Public Health Service Act) or

(2) Federally-designated Medically Underserved Area (under section 330(b)(3) of the Public Health Service Act).

PART 6—FEDERAL TORT CLAIMS ACT COVERAGE OF CERTAIN GRANTEES AND INDIVIDUALS

Sec.

AUTHORITY: Sections 215 and 224 of the Public Health Service Act, 42 U.S.C. 216 and 233.

SOURCE: 60 FR 22532, May 8, 1995, unless otherwise noted.

§ 6.1 Applicability.

This part applies to entities and individuals whose acts and omissions related to the performance of medical, surgical, dental, or related functions are covered by the Federal Tort Claims Act (28 U.S.C. 1346(b) and 2671–2680) in accordance with the provisions of section 224(g) of the Public Health Service Act (42 U.S.C. 233(g)).

§ 6.2 Definitions.

Act means the Public Health Service Act, as amended.

Attorney General means the Attorney General of the United States and any

other officer or employee of the Department of Justice to whom the authority involved has been delegated.

Covered entity means an entity described in § 6.3 which has been deemed by the Secretary, in accordance with § 6.5, to be covered by this part.

Covered individual means an individual described in § 6.4.

Effective date as used in § 6.5 and § 6.6 refers to the date of the Secretary's determination that an entity is a covered entity.

Secretary means the Secretary of Health and Human Services (HHS) and any other officer or employee of the Department of HHS to whom the authority involved has been delegated.

Subrecipient means an entity which receives a grant or a contract from a covered entity to provide a full range of health services on behalf of the covered entity.

§ 6.3 Eligible entities.

(a) *Grantees.* Entities eligible for coverage under this part are public and nonprofit private entities receiving Federal funds under any of the following grant programs:

(1) Section 329 of the Act (relating to grants for migrant health centers);

(2) Section 330 of the Act (relating to grants for community health centers);

(3) Section 340 of the Act (relating to grants for health services for the homeless); and

(4) Section 340A of the Act (relating to grants for health services for residents of public housing).

(b) *Subrecipients.* Entities that are subrecipients of grant funds described in paragraph (a) of this section are eligible for coverage only if they provide a full range of health care services on behalf of an eligible grantee and only for those services carried out under the grant funded project.

§ 6.4 Covered individuals.

(a) Officers and employees of a covered entity are eligible for coverage under this part.

(b) Contractors of a covered entity who are physicians or other licensed or certified health care practitioners are eligible for coverage under this part if they meet the requirements of section 224(g)(5) of the Act.

(c) An individual physician or other licensed or certified health care practitioner who is an officer, employee, or contractor of a covered entity will not be covered for acts or omissions occurring after receipt by the entity employing such individual of notice of a final determination by the Attorney General that he or she is no longer covered by this part, in accordance with section 224(i) of the Act.

§ 6.5 Deeming process for eligible entities.

Eligible entities will be covered by this part only on and after the effective date of a determination by the Secretary that they meet the requirements of section 224(h) of the Act. In making such determination, the Secretary will receive such assurances and conduct such investigations as he or she deems necessary.

§ 6.6 Covered acts and omissions.

(a) Only acts and omissions occurring on and after the effective date of the Secretary's determination under § 6.5 and before the later date specified in section 224(g)(3) of the Act are covered by this part.

(b) Only claims for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions are covered by this part.

(c) With respect to covered individuals, only acts and omissions within the scope of their employment (or contract for services) are covered. If a covered individual is providing services which are not on behalf of the covered entity, such as on a volunteer basis or on behalf of a third-party (except as described in paragraph (d) of this section), whether for pay or otherwise, acts and omissions which are related to such services are not covered.

(d) Only acts and omissions related to the grant-supported activity of entities are covered. Acts and omissions related to services provided to individuals who are not patients of a covered entity will be covered only if the Secretary determines that:

(1) The provision of the services to such individuals benefits patients of the entity and general populations that could be served by the entity through

community-wide intervention efforts within the communities served by such entity;

(2) The provision of the services to such individuals facilitates the provision of services to patients of the entity; or

(3) Such services are otherwise required to be provided to such individuals under an employment contract or similar arrangement between the entity and the covered individual.

(e) *Examples.* The following are examples of situations within the scope of paragraph (d) of this section:

(1) A community health center deemed to be a covered entity establishes a school-based or school-linked health program as part of its grant supported activity. Even though the students treated are not necessarily registered patients of the center, the center and its health care practitioners will be covered for services provided, if the Secretary makes the determination in paragraph (d)(1) of this section.

(2) A migrant health center requires its physicians to obtain staff privileges at a community hospital. As a condition of obtaining such privileges, and thus being able to admit the center's patients to the hospital, the physicians must agree to provide occasional coverage of the hospital's emergency room. The Secretary would be authorized to determine that this coverage is necessary to facilitate the provision of services to the grantee's patients, and that it would therefore be covered by paragraph (d)(2) of this section.

(3) A homeless health services grantee makes arrangements with local community providers for after-hours coverage of its patients. The grantee's physicians are required by their employment contracts to provide periodic cross-coverage for patients of these providers, in order to make this arrangement feasible. The Secretary may determine that the arrangement is within the scope of paragraph (d)(3) of this section.

(4) For the specific activities described in this paragraph (e)(4), when carried out by an entity (and its eligible personnel) that has been covered under paragraph (c) of this section, the Department has determined that coverage is provided under paragraph (d) of this section, without the need for specific application for an additional coverage determination under paragraph (d) of this section, if the activity or arrangement in question fits squarely within these descriptions; otherwise, the health center should seek a particularized determination of coverage.

(i) *Community-Wide Interventions.* (A) School-Based Clinics: Health center staff provide primary and preventive health care services at a facility located in a school or on school grounds. The health center has a written affiliation agreement with the school.

(B) School-Linked Clinics: Health center staff provide primary and preventive health care services, at a site not located on school grounds, to students of one or more schools. The health center has a written affiliation agreement with each school.

(C) Health Fairs: On behalf of the health center, health center staff conduct or participate in an event to attract community members for purposes of performing health assessments. Such events may be held in the health center, outside on its grounds, or elsewhere in the community.

(D) Immunization Campaigns: On behalf of the health center, health center staff conduct or participate in an event to immunize individuals against infectious illnesses. The event may be held at the health center, schools, or elsewhere in the community.

(E) Migrant Camp Outreach: Health center staff travel to a migrant farmworker residence camp to conduct intake screening to determine those in need of clinic services (which may mean health care is provided at the time of such intake activity or during subsequent clinic staff visits to the camp).

(F) Homeless Outreach: Health center staff travel to a shelter for homeless persons, or a street location where homeless persons congregate, to conduct intake screening to determine those in need of clinic services (which may mean health care is provided at the time of such intake activity or during subsequent clinic staff visits to that location).

(ii) *Hospital-Related Activities.* Periodic hospital call or hospital emergency room coverage is required by the

hospital as a condition for obtaining hospital admitting privileges. There must also be documentation for the particular health care provider that this coverage is a condition of employment at the health center.

(iii) *Coverage-Related Activities.* As part of a health center's arrangement with local community providers for after-hours coverage of its patients, the health center's providers are required by their employment contract to provide periodic or occasional cross-coverage for patients of these providers.

(iv) *Coverage in Certain Individual Emergencies.* A health center provider is providing or undertaking to provide covered services to a health center patient within the approved scope of project of the center, or to an individual who is not a patient of the health center under the conditions set forth in this rule, when the provider is then asked, called upon, or undertakes, at or near that location and as the result of a non-health center patient's emergency situation, to temporarily treat or assist in treating that non-health center patient. In addition to any other documentation required for the original services, the health center must have documentation (such as employee manual provisions, health center bylaws, or an employee contract) that the provision of individual emergency treatment, when the practitioner is already providing or undertaking to provide covered services, is a condition of employment at the health center.

[60 FR 22532, May 8, 1995; 60 FR 36073, July 13, 1995; 78 FR 58204, Sept. 23, 2013]

PART 7—DISTRIBUTION OF REFERENCE BIOLOGICAL STANDARDS AND BIOLOGICAL PREPARATIONS

Sec.
7.1 Applicability.
7.2 Establishment of a user charge.
7.3 Definitions.
7.4 Schedule of charges.
7.5 Payment procedures.
7.6 Exemptions.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); title V of the Independent Offices Appropriations Act of 1952 (31 U.S.C. 9701); and secs. 301(a) and 352 of the Public Health Service Act, as amended (42 U.S.C. 241(a) and 263).

SOURCE: 52 FR 11073, Apr. 7, 1987, unless otherwise noted.

§ 7.1 Applicability.

The provisions of this part are applicable to private entities requesting from the Centers for Disease Control and Prevention (CDC) reference biological Standards and Biological preparations for use in their laboratories.

[78 FR 43820, July 22, 2013]

§ 7.2 Establishment of a user charge.

Except as otherwise provided in § 7.6, a user charge shall be imposed to cover the cost to CDC of producing and distributing reference biological standards and biological preparations.

§ 7.3 Definitions.

Biological standards means a uniform and stable reference biological substance which allows measurements of relative potency to be made and described in a common currency of international and national units of activity.

Biological preparations means a reference biological substance which may be used for a purpose similar to that of a standard, but which has been established without a full collaborative study, or where a collaborative study has shown that it is not appropriate to establish the preparation as an international standard.

§ 7.4 Schedule of charges.

The charges imposed in § 7.2 are based on the amount published in CDC's price list of available products. These changes will reflect direct costs (such as salaries and equipment), indirect costs (such as rent, telephone service, and a proportionate share of management and administrative costs), and the cost of particular ingredients. Charges may vary over time and between different biological standards or biological preparations, depending upon the cost of ingredients and the complexity of production. An up-to-date schedule of charges is available from the Division of Scientific Resources, Centers for Disease Control,